

A2 3. (Amended) A method according to claim 1 employing an effective amount of S (-) pindolol or a salt thereof.

A3 4. (Amended) A method according to claim 1 in which effective amounts of RS pindolol or S(-) pindolol or their salts are administered in a pharmaceutical dosage form that releases the active substances in a slow or controlled fashion.

### REMARKS

As indicated in the Office Action, the references do not teach the use of racemic or S(-) pindolol for treating gastrointestinal diseases so the 35 USC § 102 reference for lack of novelty should be withdrawn.

The 35 USC § 103 obviousness rejections are also not applicable to the amended claims. The data in example 1 illustrates the surprising effectiveness of pindolol in treating non-ulcerative dyspepsia.

#### EXAMPLE 1

Eleven patients suffering from non-ulcerative dyspepsia were recruited to a clinical study and gave informed consent. All were treated with pindolol 5mg three times daily. Seven of the 11 patients showed a significant improvement in symptoms within 1 week of commencing treatment. A further patient improved in the second week. Their responses were quantified using a standard rating scale (GSRS scores). The results demonstrated a substantial improvement with a reduction in average symptom severity of approximately 68% in three weeks, with the greatest improvement observed within one week.

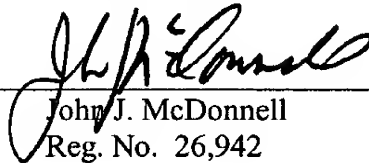
Talbe 1. Mean symptom score (average of 11 patients)

Week	Mean GSRS score
0	9
1	4.2
2	3.5
3	2.9

CONCLUSION

Allowance of the amended claim and passage of the case to issue are solicited.

Respectfully submitted,

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Application of T.G. Dinan  
Serial No: 09/687,384  
Atty Docket No. 99,829-A

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**Appendix A**  
A marked-up version of amended Claim

1. A method for preventing and treating gastrointestinal disease by means of administration of an effective amount of [an antagonist or partial agonist of 5HT<sub>1a</sub> receptors] racemic RS pindolol or a salt thereof.
3. A method according to claim 1 employing an effective amount of [one of the enantiomers] S (-) pindolol [of claim 1] or a salt thereof.
5. A method according to claim 1 in which effective amounts of RS pindolol or S(-) pindolol or their salts are administered in a pharmaceutical dosage form that releases the active substances in a slow or controlled fashion [that in turn permits administration of the active substances at lesser frequency than in claim 3].

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Application of T.G. Dinan  
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**Appendix B**  
A Clean Copy of All pending Claims

1. A method for preventing and treating gastrointestinal disease by means of administration of an effective amount of racemic RS pindolol or a salt thereof.

3. ~~2.~~ A method according to claim 1 employing an effective amount of S (-) pindolol or a salt thereof.

4. ~~3.~~ A method according to claim 1 in which effective amounts of RS-pindolol or S(-) pindolol or their salts are administered in a pharmaceutical dosage form that permits rapid release of the active substances.

5. ~~4.~~ A method according to claim 1 in which effective amounts of RS pindolol or S(-) pindolol or their salts are administered in a pharmaceutical dosage form that releases the active substances in a slow or controlled fashion.

6. ~~5.~~ A method according to claim 1 in which the gastrointestinal diseases are characterised as non-ulcerative dyspepsia or irritable bowel syndrome or chemotherapy-associated disorders of motility, including nausea.

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